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(12) UK Patent Application (19) GB (11) 2 203 342 (13) A

(43) Application published 19 Oct 1988

(21) Application No 8708328

(22) Date of filing 7 Apr 1987

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(51) INT CL'
A61L 27/00

(52) Domestic classification (Edition J):
A5R AG

(56) Documents cited

GB A 2073024	GB 1565828	GB 1552388
GB 1445177	GB 1317417	EP A 0177288
EP A2 0067929	EP A2 0041111	EP A1 0000949
WO A1 8403036	WO A1 8303752	WO A1 8201647
WO A1 8102667	US 4167045	US 3688318

Note: GB A 2073024 and WO A1 8102667
EP A1 0000949 and US 4167045 are equivalent;

(58) Field of search
A5R
Selected US specifications from IPC sub-class
A61F

(54) Radio-opaque tracer for surgical implants

(57) Medically safe metallic material, in particular gold, is used as a radiologically opaque part of a surgical soft tissue implant such as vascular prostheses and prostheses for the surgical replacement of ligaments and tendons.

GB 2 203 342 A

RADIO-OPAQUE TRACER FOR SURGICAL IMPLANTS

When soft tissue is replaced in a surgical procedure whereby the whole or a part of that soft tissue is replaced or augmented, there is no convenient method by which post-operative evaluation of the procedure can be made by non-invasive technique, since the soft tissues and the implant are usually invisible to X-rays.

By way of specific example, the Leeds-Keio prosthetic ligament, as described in European Patent Application 0 126 520 is constructed using a leno or mock-leno weave from a polyester yarn, which is invisible to X-rays. The prosthesis is fixed into place by the insertion within the tubular part of the prosthesis of a plug of bone. The gap between the bone plug and the host bone through which the prosthesis runs, becomes invaded by tissue, which gradually becomes calcified as new bone forms, hence anchoring the prosthesis firmly in place. The prosthesis is foraminous, having areas with perforations of about 0.01 cm^2 so that tissue ingrowth is promoted. A surgeon may wish to study by X-ray or similar method any changes that may have occurred to the prosthesis and the site adjacent to it, either non-invasively, or by way of preparation for an invasive investigation. For example, during early investigations to develop the technique for implantation of this prosthesis, young pigs were used. Within one young growing pig after a long post-op rativ period, the pig grew considerably in size. The growth produced a considerable increase in the

t nsion upon the polyester prosthesis, which r sulted in the site of the bone plug shifting within the host bone, and causing bone deformity. Therefore such an operation is contra-indicated in humans when epiphyseal bon growth is still active. Should investigation be required of movements of bone plugs and the associated ligament prosthesis within young animals, a simple technique for investigation of such movements is necessary. X-rays and similar radiological methods provide the investigative technique, but many prostheses are invisible to the X-rays. Other monitoring investigations may require to be made upon an implant of a ligament, tendon or vascular prosthesis, which would b simplified by incorporating a proportion of a safe radio-opaque material.

Previously, the approach to the monitoring of textile products within the body has been to use a textile fibre such as polypropylene which contains a high proportion of a radio-opaque substance such as barium sulphate. Such a fibre is sometimes used within items such as swabs, when a simple technique is required to locate a swab within the body to simplify its speedy removal. The difficulty with using such a fibre within a prosthesis is that the fibre containing such as barium sulphate is not intended to remain within the body for a long period, therefore an investigation of the long-term effects of the radio-opaque substance on the body is not necessary. To investigate these long-term effects would be both costly and take a consid rabl length of time.

The pr sent invention provides a simple and safe method of evaluating post-operatively the soft-tissue implant by including a m dically safe m tallic material within the implant which is otherwise invisible to xternal scanning techniques such as X-rays and other methods, yet not substantially interfere with the performance of the implant. The chosen material therefore will usually have to be ductile or otherwise in a form such that it remains highly flexible. The material chosen is generally described as being radio-opaque.

Suitable metallic materials are those which are known to be medically safe to humans, such as high purity metals, e.g. gold, platinum, titanium, palladium and their alloys, and stainless steel. Gold is particularly preferred since it is well known as having no long term ill-effects when used within the body. The metallic form is suitable in elemental or alloyed form.

A specific embodiment of the invention uses a gold wire of diameter 0.1 to 0.5mm, of purity greater than 95% gold, preferably greater than 99%. A particularly suitable form of gold wire is that known as 'fine gold' which has a diameter of about 0.3mm and a purity of about 99.98% gold. This is woven as a single end weaving in the same heald on the loom as one of the main warp yarns of a ligament prosthesis as described in European Patent Application 0 126 520. Such gold wire is of sufficient diameter to be identifiable in a X-ray photograph of a bone, yet of sufficiently low diameter to be reasonably flexible for the purposes of weaving. As

well as incorporating the wire within the prosthesis during the weaving process, the wire can also be incorporated after weaving by hand or machine, such as by using a needle in conventional sewing.

Instead of a single wire, four wires within the prosthesis will provide more information from X-ray photographs than a single end. Unfortunately, the high cost of gold may render the advantage of using more than one end of gold wire per prosthesis economically unacceptable.

In a further embodiment of the invention, a vascular implant of polyester textile fibre, which may have been knitted, woven or braided, is subjected to a coating technique such as vacuum deposition of a fine layer of metal such as gold over a whole or a part of its surface, sufficient gold being used to provide sufficient scattering of the X-rays to render the transplant visible by X-ray technique. By only depositing gold over a part of the surface, by shielding parts of the prosthesis during deposition of the metal, movement of the prosthesis within the body becomes more evident. The coating may be by another deposition technique, such as the chemical precipitation of the metal onto the surface of the fibres forming the prosthesis. Furthermore, the metal may be deposited within the fibre itself, during the fibre spinning process. This embodiment has the advantage of shielding the metallic component from direct contact with body tissues, and hence allow the use of metals whose medical safety is less well characterised.

CLAIMS

1. A soft-tissue implant containing a proportion of medically safe metallic material.

2. A soft-tissue implant as claimed in claim 1, containing a metallic material in such form and amount that it is detectable by external scanning techniques, but does not substantially interfere with the performance of the implant.

3. A soft-tissue implant according to claim 1 or 2, where the metallic material is in the form of a wire.

4. A soft-tissue implant according to claim 3, where the metallic material is in the form of a wire of between 0.1mm and 0.5mm.

5. A soft-tissue implant according to claim 1 or claim 2, where the metallic material is in the form of a coating upon a textile fibre.

6. A soft-tissue implant according to claim 5, where the metallic material is coated upon the fiber by vacuum deposition.

7. A soft-tissue implant according to claim 5, where th metallic material is coated upon the fiber by chemical techniques.

8. A soft-tissue implant according to claim 1 or claim 2, where th metallic material is incorporated within the fibre during the fibre spinning process.

9. A soft-tissue implant according to any one of claims 1 to 8, where the metallic material is gold.

10. A soft-tissue implant according to any one of claims 1 to 9, where the gold is of a purity of greater than 95%.

11. A soft-tissue implant according to claim 10, where the gold is of a purity of greater than 99%.

12. A soft-tissue implant according to any of claims 1 to 11, where the implant is a woven textile.

13. A soft-tissue implant according to claim 12, where the implant is mock-leno or leno woven in which the warp threads are locked with respect to the weft threads.

14. A soft-tissue implant according any of the claims 1 to 11, where the implant is a knitted textile.

15. A soft-tissue implant according to any of the claims 1 to 11, where the implant is a braided textile.

16. A soft-tissue implant according to any f the claims 1 to 15, where the implant is foraminous, including an area with perforations of at least 0.01 cm^2 so that tissue

ingrowth is promoted.

17. A soft-tissue implant substantially as herein described.

18. Th use of soft-tissue implants as claimed in any one of claims 1 to 17 in surgery.

Published 1988 at The Patent Office, State House, 66 71 High Holborn, London WC1R 4TP. Further copies may be obtained from The Patent Office, Sales Branch, St Mary Cray, Orpington, Kent BR5 3RD. Printed by Multiplex techniques ltd, St Mary Cray, Kent. Con. 1/87.